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Bagaoisan et al.

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(54) **APPARATUS AND METHODS FOR INFLATING AND DEFLATING BALLOON CATHETERS**

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(60) Provisional application No. 61/430,082, filed on Jan. 5, 2011.

(51) **Int. Cl.**
A61M 25/10 (2013.01)

(52) **U.S. Cl.**
CPC ***A61M 25/10182*** (2013.11); ***A61M 25/1018*** (2013.01); ***A61M 25/10184*** (2013.11)

(58) **Field of Classification Search**
CPC A61M 25/10181; A61M 25/10182; A61M 25/10184; A61M 25/10187; A61M 25/1018
USPC 604/97.01–97.03, 99.01–99.04
See application file for complete search history.

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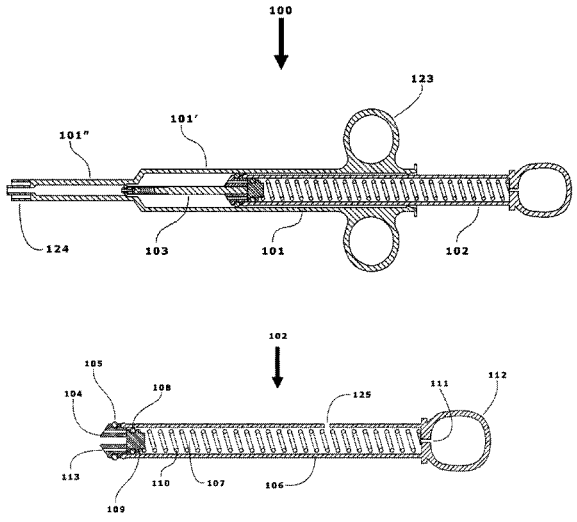
(57) **ABSTRACT**

Among the various embodiments, objects and features of the present invention may generally be noted an inflation/deflation syringe that enables one-handed operation to inflate a medical device to a given pressure or volume and one-handed operation to deflate said medical device.

23 Claims, 12 Drawing Sheets



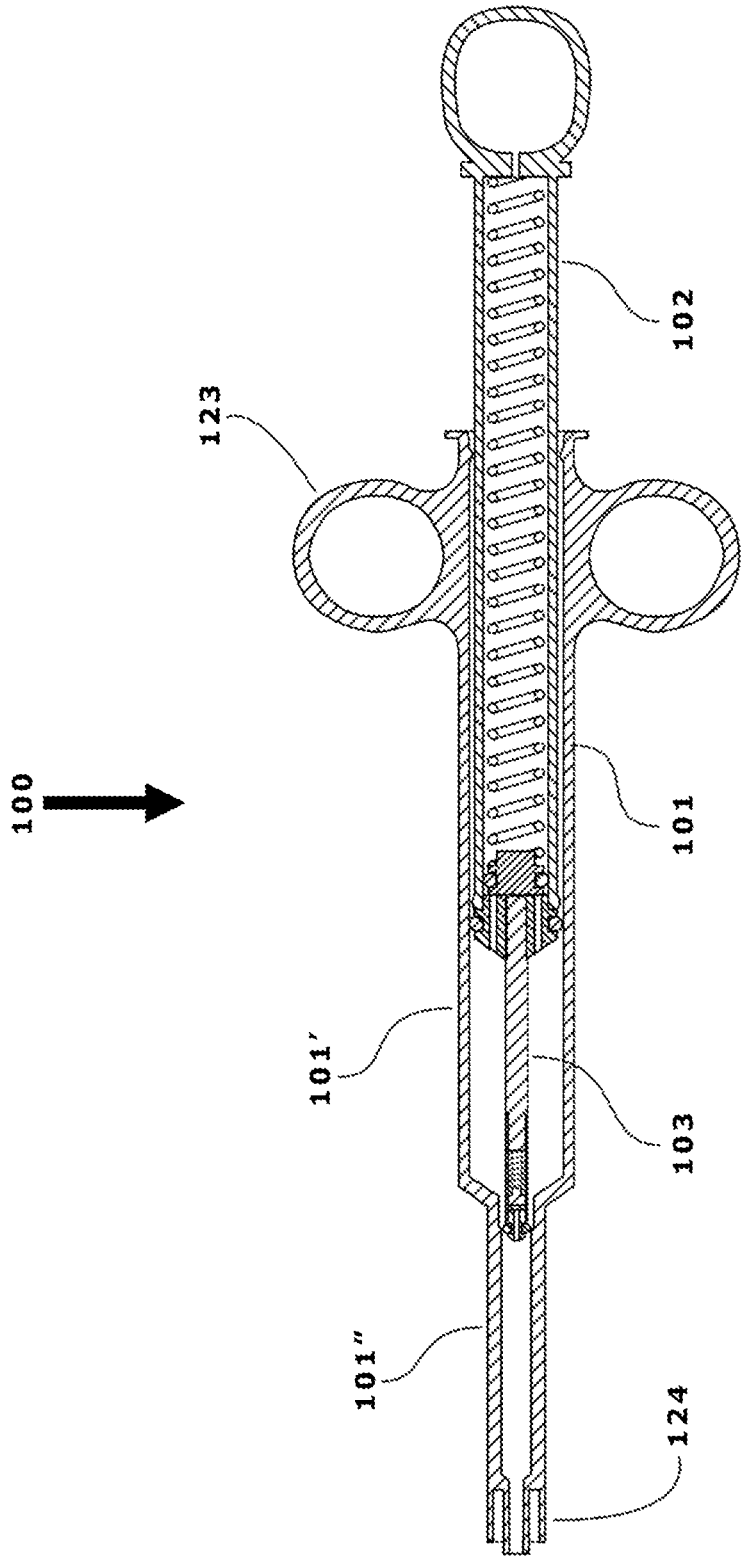


FIG. 1A

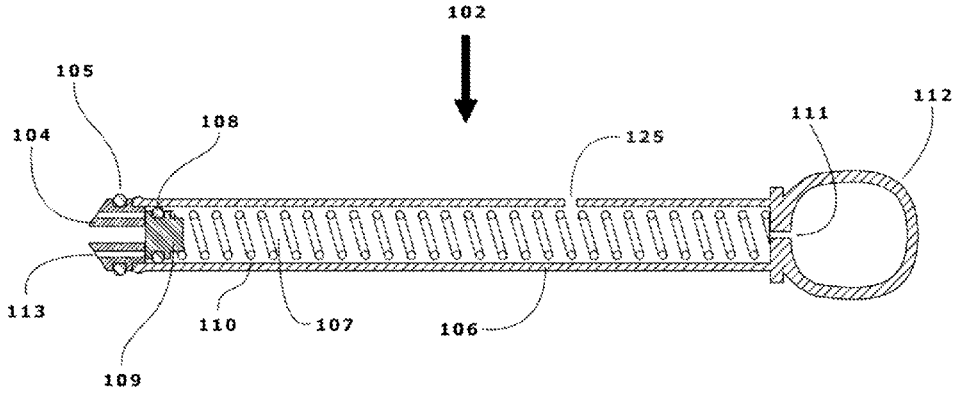

102
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FIG. 1B

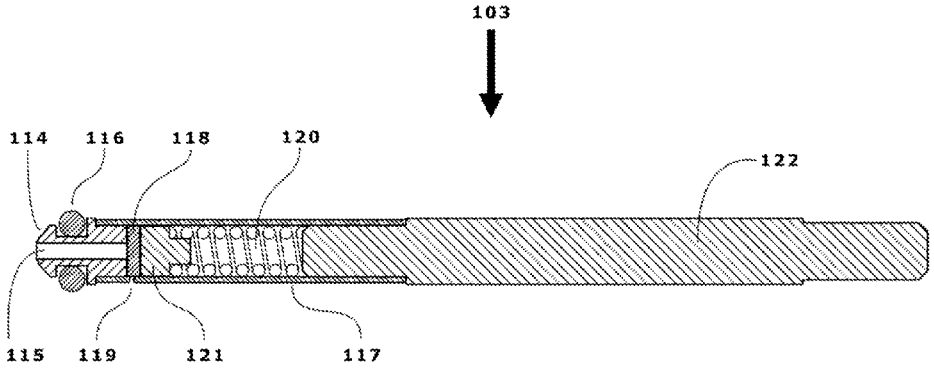
103
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FIG. 1C

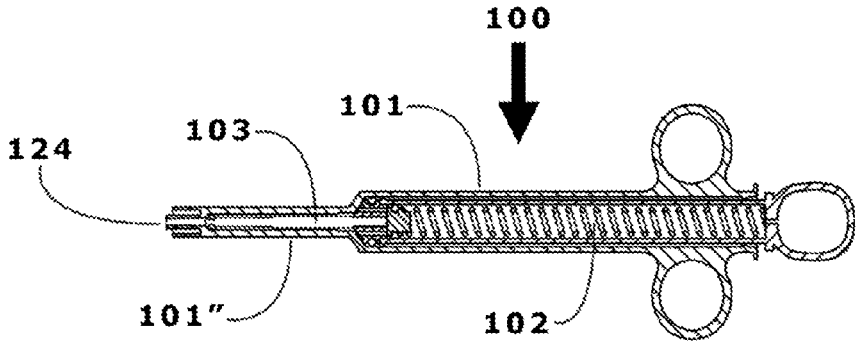

FIG. 2A

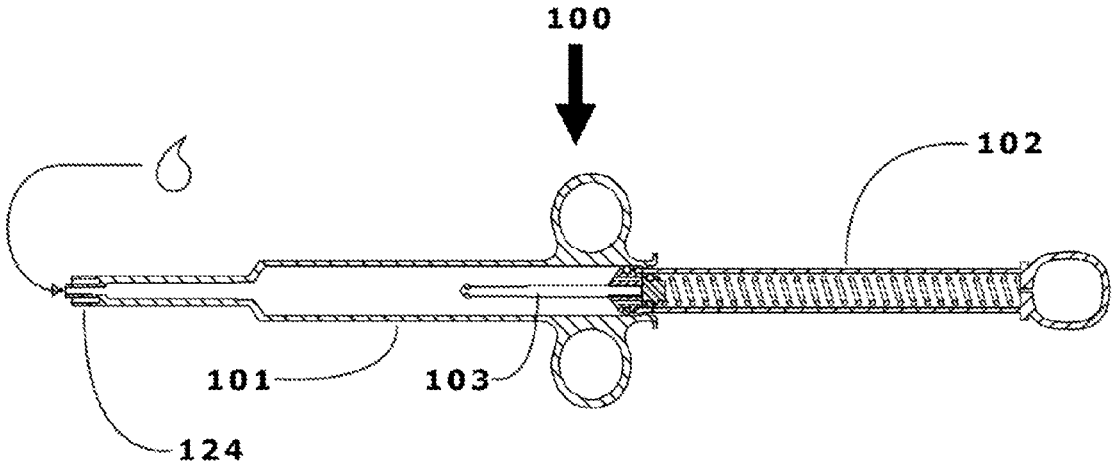

FIG. 2B

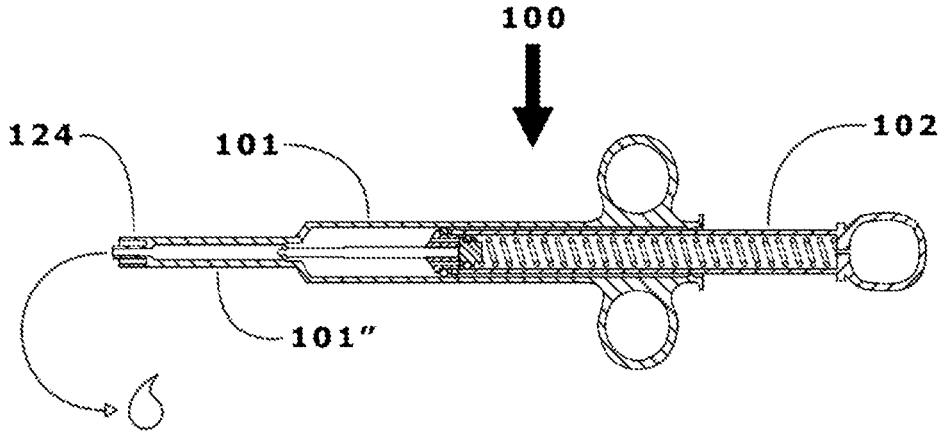

FIG. 2C

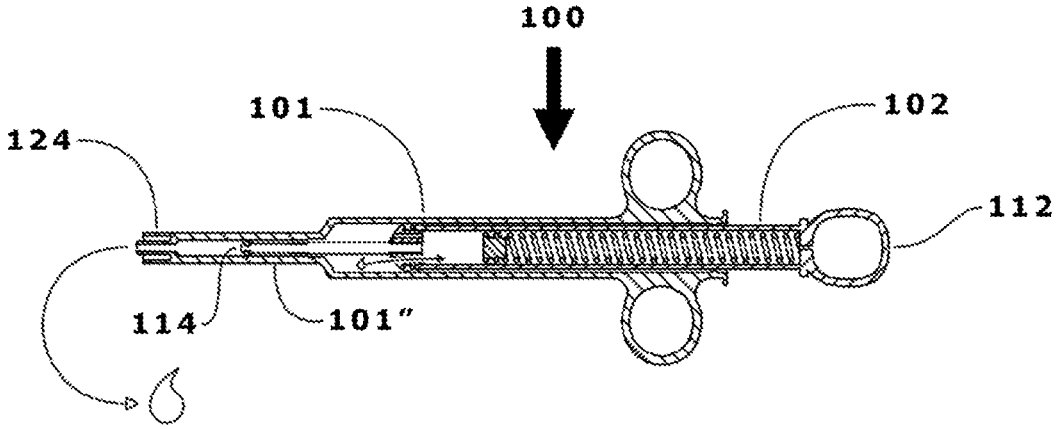

FIG. 2D

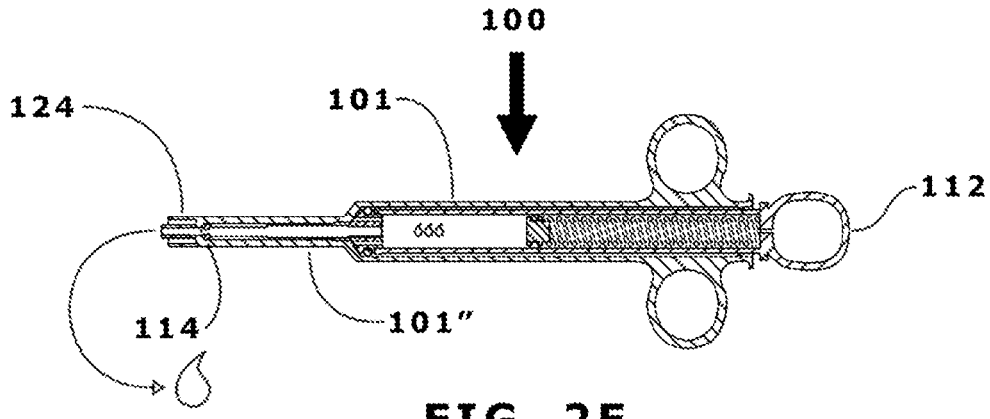

FIG. 2E

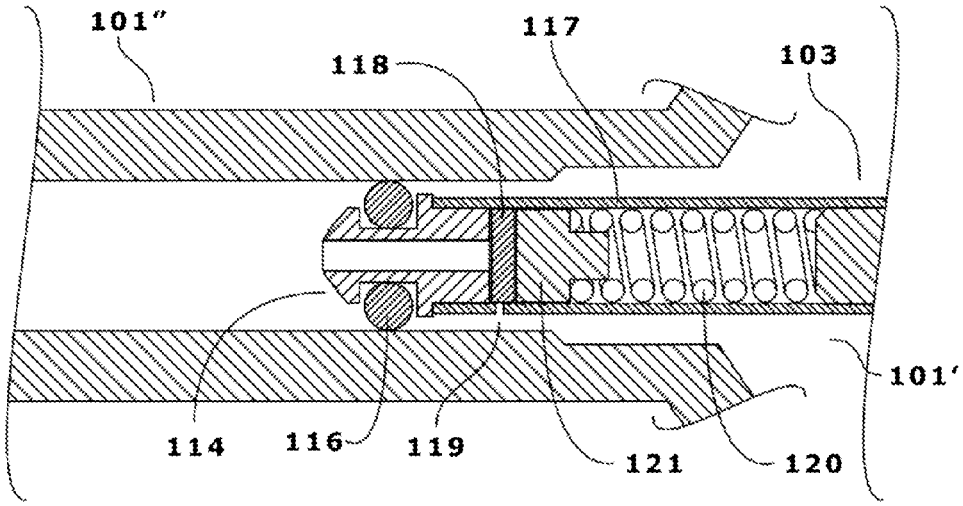
101"
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FIG. 3A

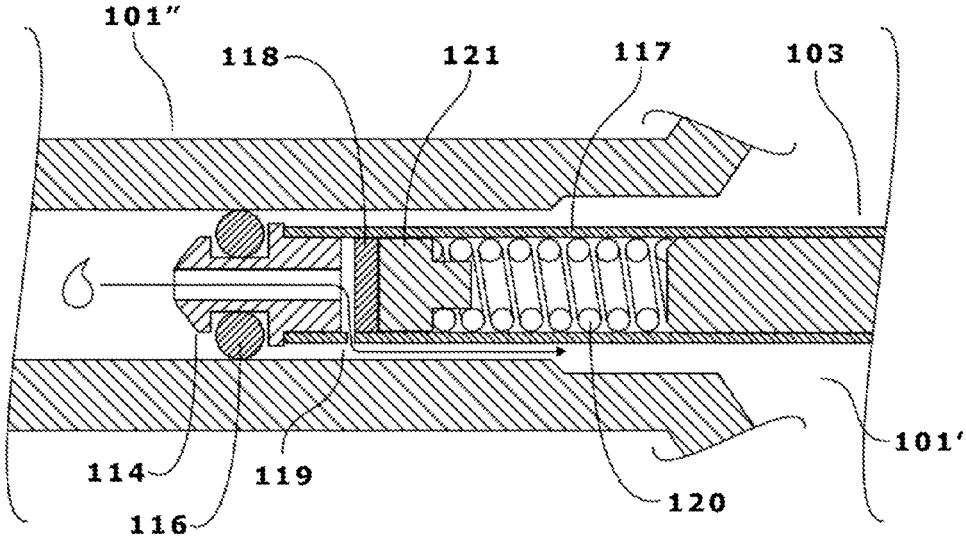
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FIG. 3B

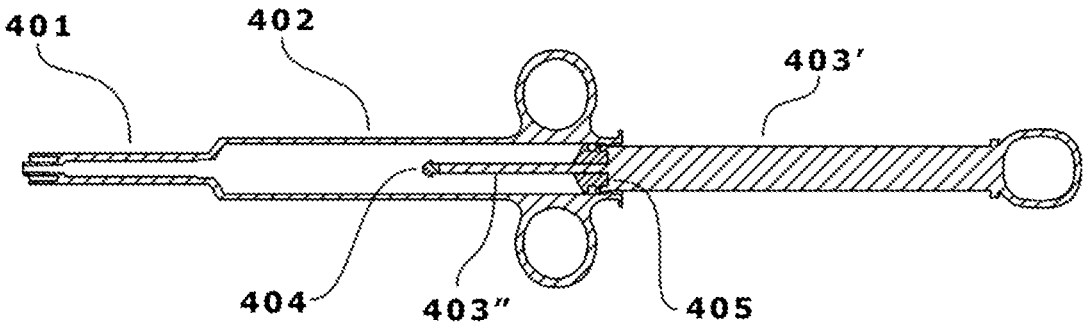

FIG. 4A

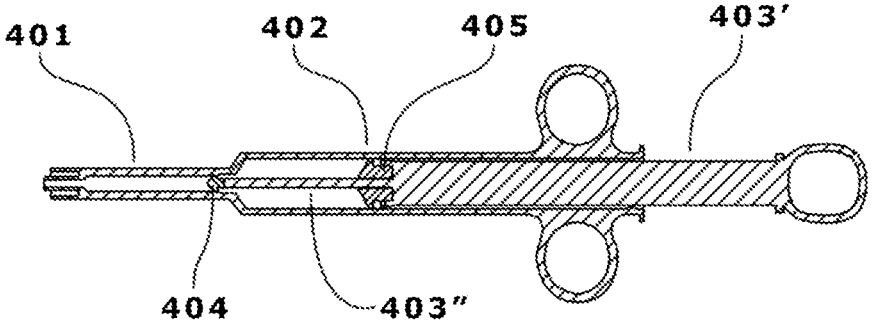

FIG. 4B

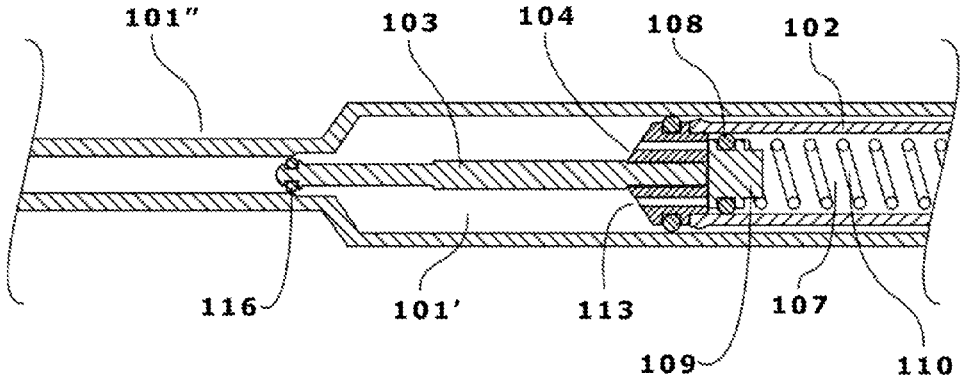
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FIG. 5A

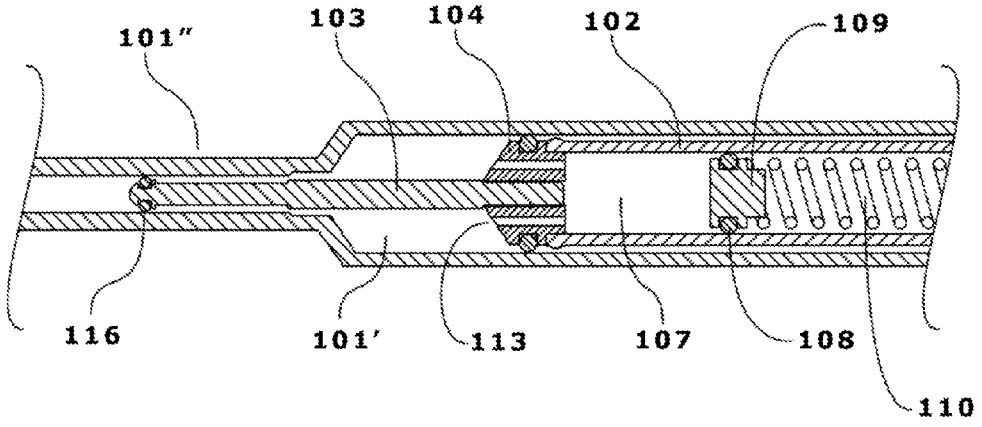
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FIG. 5B

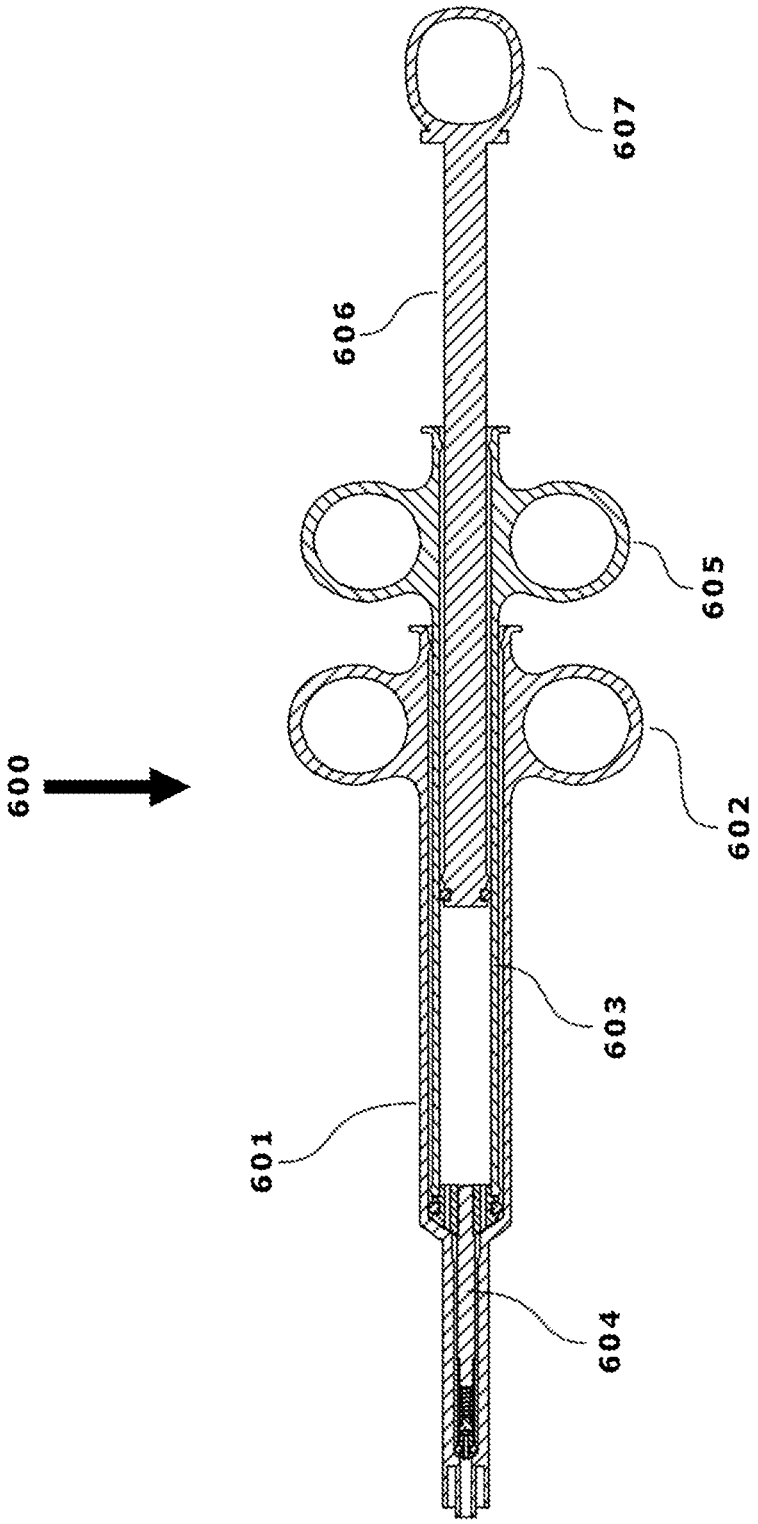

FIG. 6

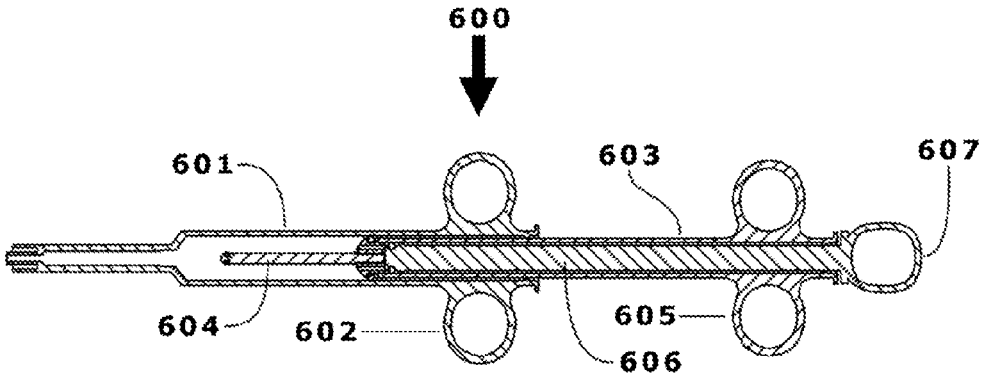

FIG. 7A

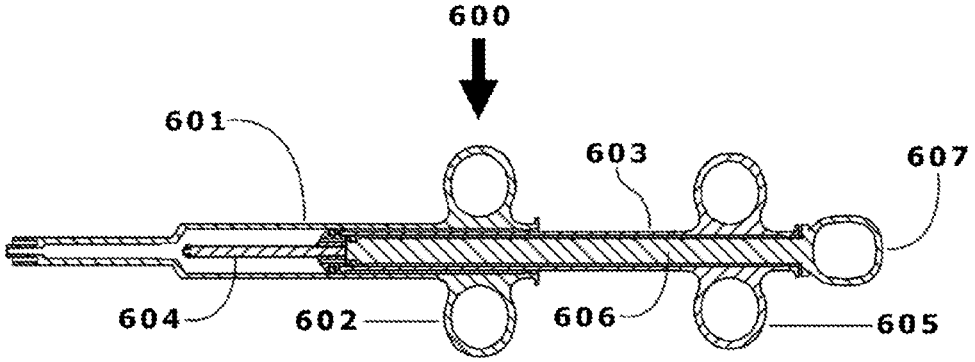

FIG. 7B

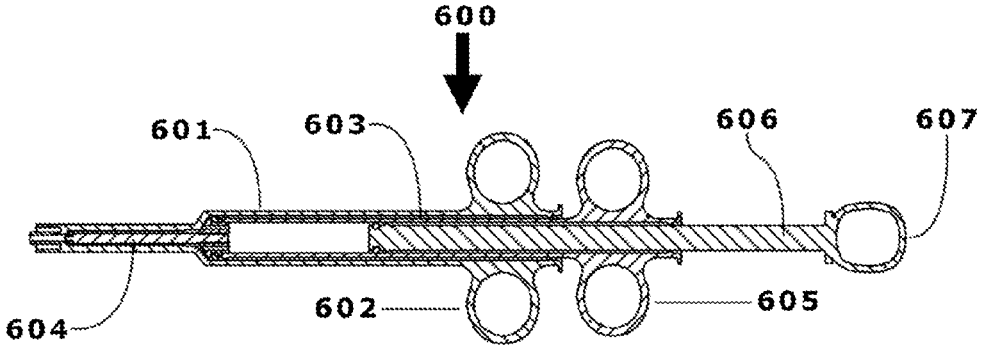

FIG. 7C

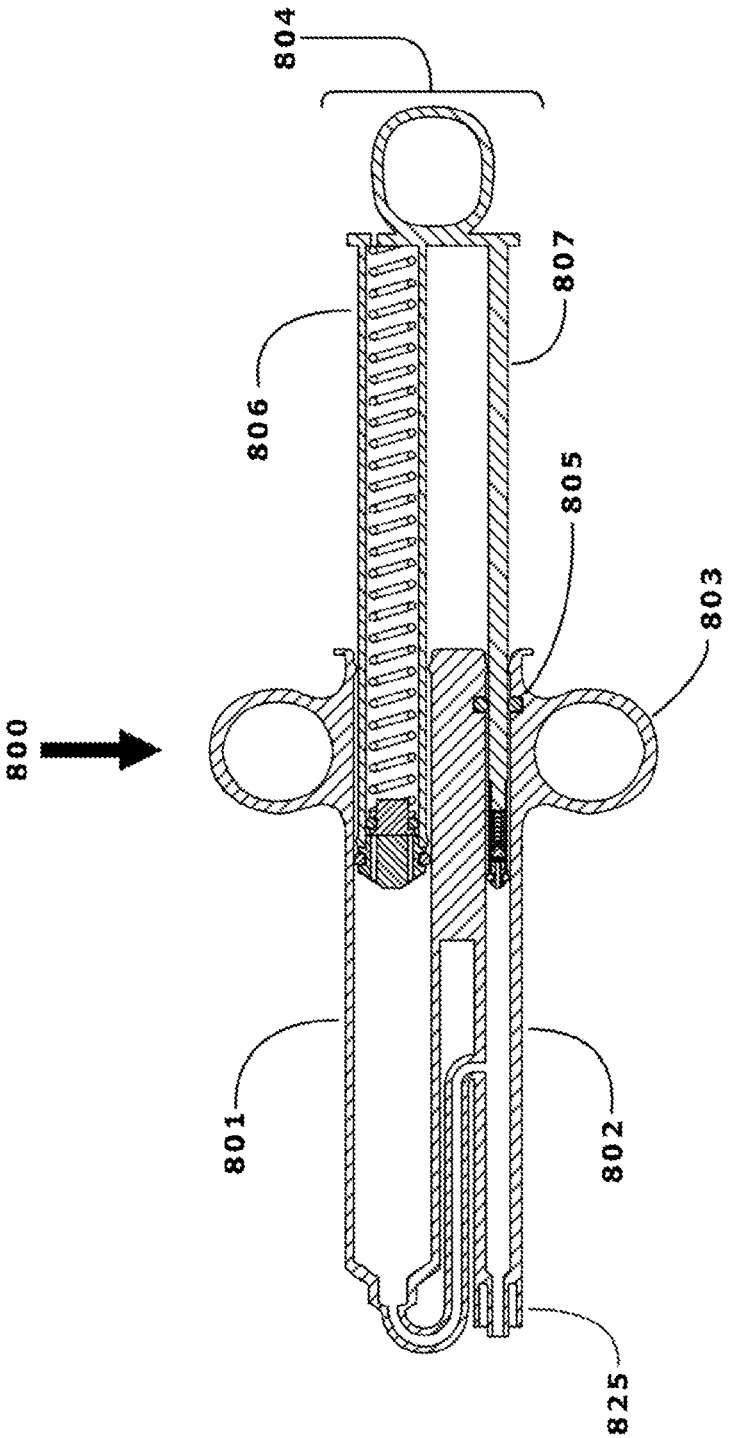

FIG. 8A

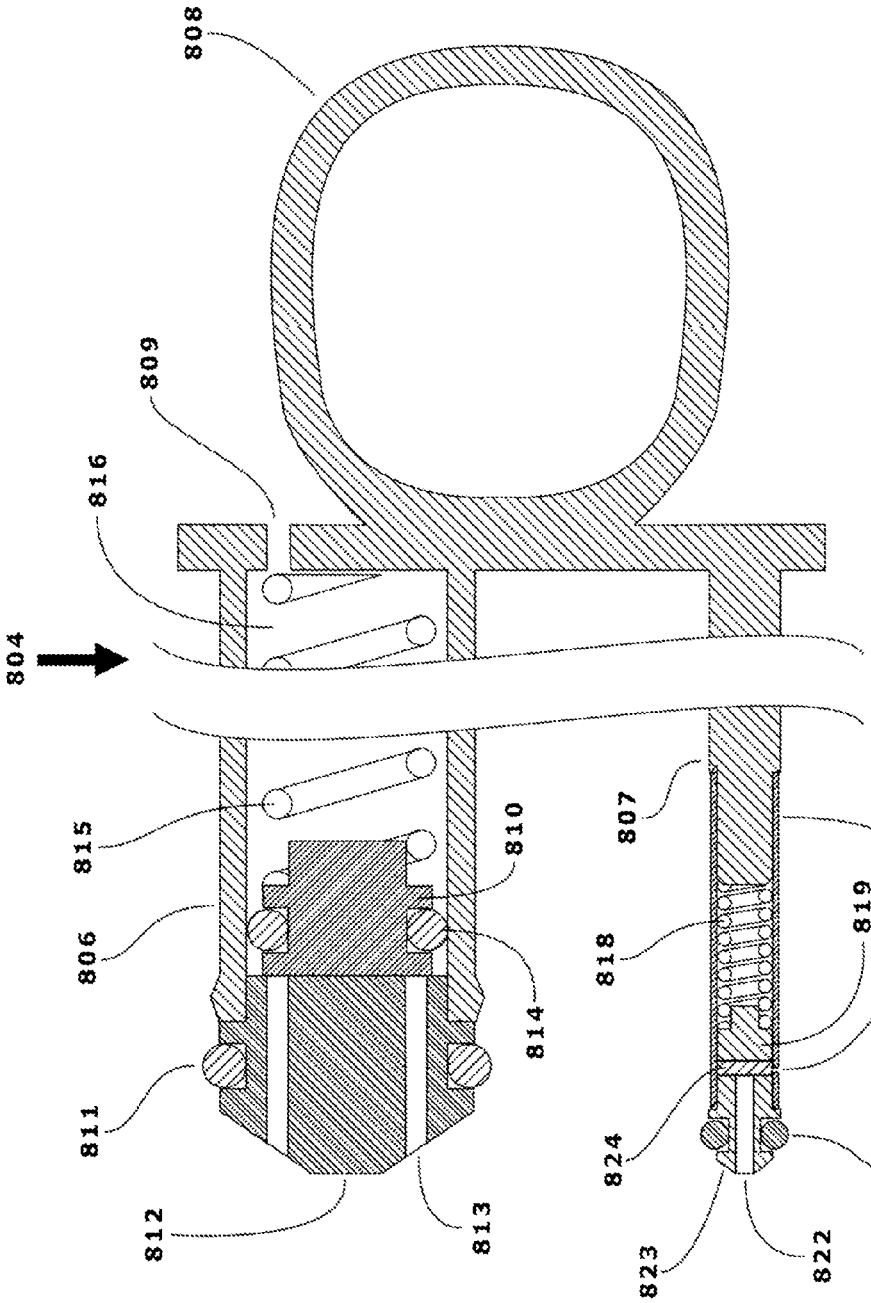
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FIG. 8B

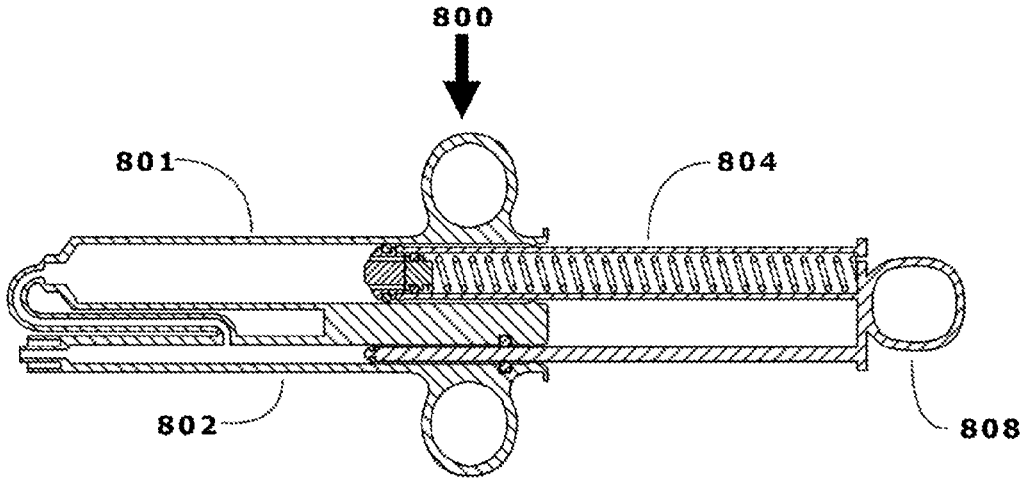

FIG. 9A

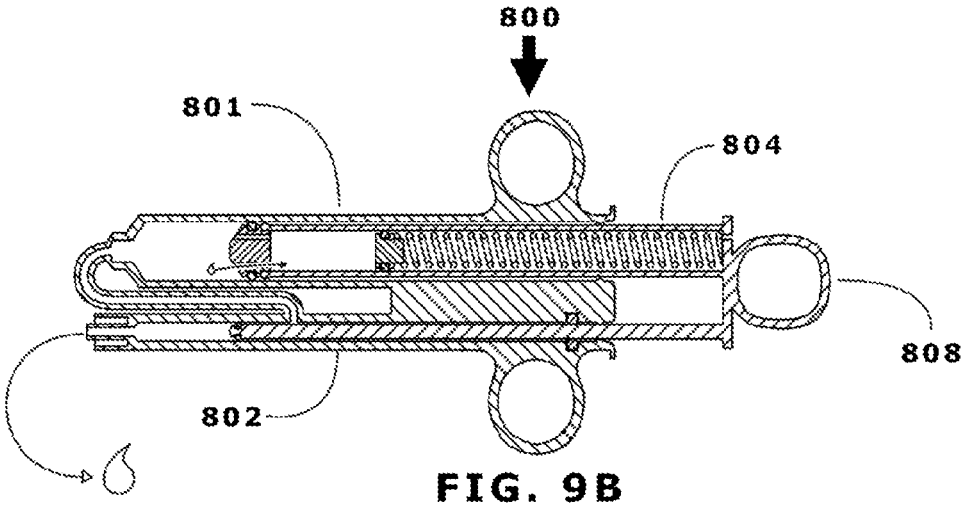

FIG. 9B

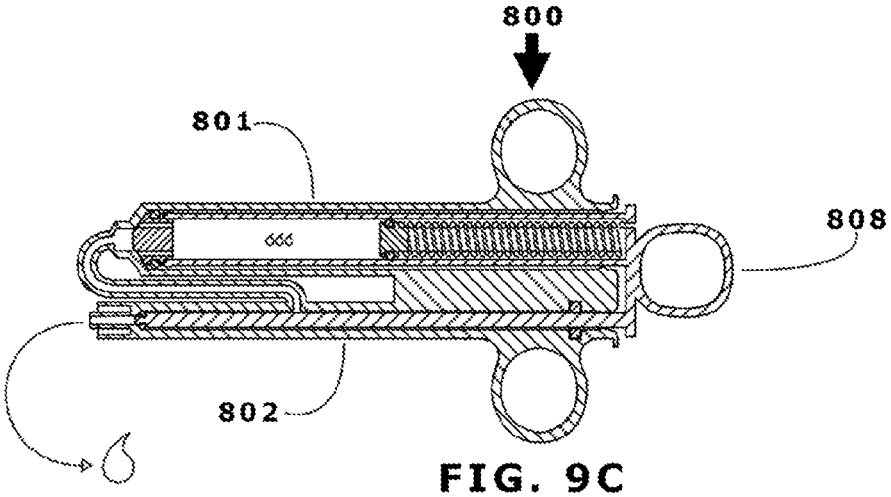

FIG. 9C

APPARATUS AND METHODS FOR INFLATING AND DEFLATING BALLOON CATHETERS

CROSS-REFERENCE TO RELATED APPLICATIONS

Pursuant to 35 U.S.C. §119(e), this application claims priority to U.S. Provisional Application No. 61/430,082 filed on Jan. 5, 2011, the disclosures of which is herein incorporated by reference in its entirety.

FIELD OF THE INVENTION

This invention generally relates to medical procedures within the human or mammalian body that utilize an inflation and/or deflation device to inflate or deflate a balloon or an inflatable membrane in procedures such as angioplasty, vertebroplasty and sinuplasty.

BACKGROUND

The use of the various devices in medical procedures entail a fair degree of manual dexterity on the part of the physician performing the procedures and frequently require the aid of one or more assistants to successfully complete the procedures. One such procedure is the inflation and deflation of balloon systems such as those employed in angioplasty, vertebroplasty, and sinuplasty with standard inflation devices. Device preparation which involves purging or evacuation of air from the balloon systems can be particularly demanding, commonly requiring the use of both hands of a single operator. Many of the medical procedures performed using balloon systems require the physician to use both hands in order to maneuver, position and hold these medical devices during the inflation or deflation steps, thus presenting the need for a second operator to accomplish procedure.

A number of commercial products are available that attempt to address one or more of the challenges associated with controlling the inflation and deflation of a balloon system. Many of these products are focused on providing precise control over the amount of pressure that is applied to the expandable member of the balloon system, as a large contingent of dilatation procedures require a relatively high amount of pressure in order to properly displace tissue, plaque, bone and the like. For example, many commercial available inflation devices comprise a syringe with a pressure gauge attached, wherein the syringe plunger is free to move longitudinally within the inner bore of the syringe barrel by pulling on a handle provided on the syringe plunger proximal end. The action of retracting the syringe plunger proximally provides a vacuum within the syringe to draw fluid or air into the syringe barrel. Conversely, pushing on the handle of the syringe plunger discharges the fluid or air out of the syringe. In a closed system (e.g. when the inflation device is attached to a balloon catheter) a sealing member (typically attached to the distal end of the syringe plunger) acts as a gasket to prevent fluid or air to leak around the gap between the inner wall of the syringe barrel and the outer surface of the syringe plunger when the syringe plunger is advanced towards the distal end of the inflation device (in order to generate pressure) or retracted proximally (in order to generate vacuum). The sealing member attached at the distal end of the syringe plunger allows the fluid or air within the closed system (the inflation/deflation device and the coupled medical device such as balloon catheter) to be compressed, increasing the internal pressure as the plunger continues to advance distally. The operator can observe the reading on the pressure gauge to ascertain that magnitude of pressure within the system. Another mechanism of inflation comprises a syringe plunger that is threaded, wherein the thread is engaged with an element of the device so that the longitudinal movement in the distal direction within the syringe barrel is effected by rotation of the threaded syringe plunger thus building up pressure within the device. The descriptions of these inflation devices are referenced in U.S. Pat. Nos. 4,743,230, 4,832,692, 5,507,727, and 7,530,970 which have been incorporated herein by reference. Other designs such as the locking syringe described in U.S. Pat. Nos. 5,047,015, 5,057,078, and 5,209,732 (herein incorporated in full by reference) allow for the selection and maintenance of a given inflation pressure.

Another method of simplifying the inflation and/or deflation of a balloon or other expandable member is illustrated in devices that allow for a pre-selected level of negative pressure to be applied and maintained without constant effort on the part of the operator. One example of this type of design is the VacLok® series of syringes available from Merit Medical. These devices comprise a polycarbonate syringe body with a stop pin and a plunger with locking fins that prevents relative motion of the plunger with respect to the syringe body when the fins are engaged with the stop pin. Vacuum is applied and maintained by retracting the syringe plunger to create a desired negative pressure, then rotating the plunger to position one of the locking fins proximal to the stop pin. The interference between the locking fin and the stop pin prevents distal motion of the plunger and the release of negative pressure. These types of designs are taught in U.S. Pat. No. 5,215,536 and are herein incorporated by reference.

Another typical inflation/deflation syringe set up that may be used for inflation and deflation of a medical device such as balloon catheter comprises a small volume syringe (e.g. 1 ml syringe), a large volume syringe (e.g. 10 ml syringe) and a manifold (e.g. 3 way manifold or stopcock) assembled together. The small volume syringe is used to provide high inflation pressures with minimal effort (due to the relatively small syringe plunger cross section), the large volume syringe is used to apply vacuum for deflation as well as serve as a reservoir for the inflation fluid media, and the manifold or stopcock functions to open or close ports enabling communication between the balloon catheter and the desired syringe. The use of the large syringe is needed as the small syringe is not capable of producing the magnitude of vacuum required for timely to deflation of the balloon, nor does it hold a sufficient volume of fluid to compensate for the void volume of the balloon catheter, inflate the balloon to a neutral pressure, and further increase the pressure in the balloon to the desired level. The method of inflation or deflation involves rotating the valve of the manifold or stopcock in order for the balloon catheter to communicate with the inflation syringe or the deflation syringe. For example, a high pressure balloon may be inflated by rotating the valve of the manifold or stopcock to open a flow path between the larger syringe and the balloon catheter. After evacuating the air in the balloon catheter, the larger syringe in depressed to fill the void volume of the balloon catheter and begin inflating the balloon. At this point, the force required to further inflate the balloon exceeds the amount that can be comfortably applied by the operator. The valve of the manifold or stopcock is rotated further to close the flow path between the larger syringe and the balloon catheter and open a flow path between the smaller syringe and the

balloon catheter. The operator continues to inflate the balloon to the desired pressure by depressing the smaller syringe. Once the desired pressure has been achieved, the valve of the manifold or stopcock is rotated to close all flow paths between the syringes and the balloon catheter. Deflation of the balloon is achieved by rotating the valve of the manifold or stopcock to open a flow path between the larger syringe and the balloon catheter and retracting the plunger of the larger syringe to generate a negative pressure in the syringe barrel. The negative pressure draws fluid out of the balloon catheter and deflates the balloon. In this set up, it is apparent that there is an added operator burden or difficulty since the operation involves several manipulations of a stopcock or manifold in order for the system to operate correctly.

While these inflation devices have utility, they are not the most efficient and convenient for the physician and medical staff to use in the field due to the need for two hands to successfully operate the devices, the ergonomics and bulk of the current designs, and the number steps needed to prepare and deploy the inflation mechanism.

An inflation and/or deflation device that would simplify the dilation of an expandable member, such as a balloon catheter, that can be successfully operated with one hand would relieve the burden placed on the physician operator and associated staff during often complex medical procedures, and thus potentially presents a labor cost savings.

RELEVANT LITERATURE

U.S. Pat. Nos. 4,743,230; 4,832,692; 5,047,015; 5,057,078; 5,209,732; 5,215,536; 5,507,727; and 7,530,970.

SUMMARY OF THE INVENTION

This invention is directed to improve the inflation/deflation of balloon dilation systems as used in angioplasty, vertebroplasty, sinuplasty, and similar procedures by allowing a user to achieve a high inflation pressure with a single hand.

This invention relates to a device that has the ability to inflate a balloon or other inflatable structures.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is best understood from the following detailed description when read in conjunction with the accompanying drawings. It is emphasized that, according to common practice, the various features of the drawings are not to-scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawings are the following figures.

FIGS. **1**A-**1**C depict cross-sectional views of an embodiment of the invention comprising a pressure limiting feature and a series deflation and inflation syringe arrangement.

FIGS. **2**A-**2**E depict a method of operation of the embodiment of the invention illustrated in FIGS. **1**A-**1**C.

FIGS. **3**A-**3**B depict a magnified view of the operation of the pressure control mechanism.

FIGS. **4**A-**4**B depict a serial syringe arrangement without incorporating the additional features of the present invention.

FIGS. **5**A-**5**B depict a magnified view of the deflation plunger during the inflation process.

FIG. **6** depicts a cross section of an embodiment of the invention comprising a movable plunger.

FIG. **7**A-**7**C depict a method of operation of the embodiment of the invention illustrated in FIG. **6**.

FIGS. **8**A-**8**B depict cross-sectional views of an embodiment of the invention comprising a pressure limiting feature and a parallel deflation and inflation syringe arrangement.

FIG. **9**A-**9**C depict a method of operation of the embodiment of the invention illustrated in FIGS. **8**A-**8**B.

DETAILED DESCRIPTION

Before the present invention is described, it is to be understood that this invention is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, some potential and preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. It is understood that the present disclosure supersedes any disclosure of an incorporated publication to the extent there is a contradiction.

It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a compound" includes a plurality of such compounds and reference to "the polymer" includes reference to one or more polymer and equivalents thereof known to those skilled in the art, and so forth.

The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

FIGS. **1**A-**1**C illustrate one embodiment of the invention. Inflation/deflation syringe **100** is comprised of a syringe barrel **101**, a deflation plunger **102**, and an inflation plunger **103**. The syringe barrel **101** is comprised of at least two integrated syringe barrel chambers, **101'** and **101"**, with at least two different cross sectional inner diameters, preferably oriented in a serial configuration. The syringe barrel

101 configuration in the preferred embodiment comprises a smaller volume syringe barrel chamber **101"** (e.g. with a volume capacity of about 1 ml), located in series and preferably distal to the larger volume syringe barrel chamber **101'** (e.g. with a volume capacity equal to or greater than 5 ml). The smaller volume syringe barrel chamber **101"** is dimensioned to have a relatively small inner diameter and is used as the inflation chamber. The larger volume syringe barrel chamber **101'** is dimensioned to have a larger inner diameter relative the smaller volume syringe barrel and is used as the deflation chamber as well as a reservoir for inflation fluid media such as air or liquid. Disposed within the syringe barrel **101** are deflation plunger **102** and inflation plunger **103**, oriented in series, each plunger sized to fit inside one of the individual inner diameters of the syringe barrel **101**. The smaller diameter inflation plunger **103** fits inside the smaller syringe barrel chamber **101"** and the larger diameter deflation plunger **102** fits inside the larger syringe barrel chamber **101'**. The distal most tip of syringe barrel **101** comprises a port connector **124** that enables fluid and/or air communication between inflation/deflation syringe **100** and an external device. Port connector **124** may include but is not limited to fixed male or female luer lock fittings, rotating male or female luer lock fittings, hose barbs, slip luers, quick release fittings, and the like. In place of a port connector provided at the distal end of the syringe barrel **101**, an extension line or tubing (not shown) may be permanently attached to the distal end of the syringe barrel **101** and the port connector **124** may attached to the distal end of the extension line (not shown). Syringe barrel **101** also comprises at least one ring **123** or a similar feature, including but not limited to flanges, indentations, wings, bars, grips, and the like, that may be used by the operator to allow the syringe body to be single-handedly held and to provide stability when advancing or retracting the deflation plunger **102**. Syringe barrel **101** may be fabricated from materials known in the art, including but not limited to polycarbonate, polypropylene, polymethylmethacrylate, PET, PEEK, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof, and may be transparent, translucent, opaque, or any gradient thereof.

As shown in FIG. **1**B, deflation plunger **102** further comprises a deflation plunger tip **104**, deflation plunger tip port **113**, deflation plunger seal **105**, deflation plunger body **106**, deflation plunger chamber **107**, piston seal **108**, piston **109**, piston return spring **110**, pressure release port **111**, media release port **125**, and plunger ring **112**. Deflation plunger body **106** may be fabricated from materials known in the art, including but not limited to polycarbonate, polypropylene, polymethylmethacrylate, PET, PEEK, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof, and may be transparent, translucent, opaque, or any gradient thereof. Deflation plunger tip **104** is joined the distal end of deflation plunger **106** using methods known in the art including, but not limited to press fitting, adhesive bonding, ultrasonic welding, threading/tapping, heat fusing, overmolding, use of a set screw, and the like and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, PTFE, stainless steel, brass, aluminum, titanium and the like or combinations thereof. The deflation plunger tip **104** and the deflation plunger body **106** may be integrated and manufactured as single component by means of commonly known fabrication techniques such as machining, injection molding, casting, and the like. The deflation plunger tip **104** may comprise at least one deflation plunger tip port **113**. Deflation plunger tip port **113** may be fabricated using methods known in the art including, but not limited to laser cutting and or engraving, mechanical machining, electrical discharge machining, chemical etching, and the like. Alternatively, deflation plunger tip port **113** may be formed in deflation plunger tip **104** as a feature of deflation plunger tip **104** during a molding process. Deflation plunger seal **105** is sized and arranged such that it provides an air and/or fluid tight seal between the deflation plunger tip **104** and the inner surface of larger syringe barrel **101'** and may be fabricated from materials including, but not limited to polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, polyethylene, and the like. While deflation plunger seal **105** is depicted as an o-ring in FIG. **1**B, it should be clear to those of skill in the art that equivalent components such as gaskets may be interchanged with deflation plunger seal **105**. For example, deflation plunger seal **105** may be an integral part of deflation plunger tip **104**, such as one or more flanges molded, machined, or otherwise manufactured as a feature of deflation plunger tip **104** that provides an air and/or liquid tight seal between deflation plunger tip **104** and the inner surface of larger syringe barrel **101'**. Piston **109** coaxially resides within deflation plunger chamber **107** and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, PTFE, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof. Piston **109** is biased by piston return spring **110** such that the distal face of piston **109** is positioned against the proximal face of deflation plunger tip **104**. Piston seal **108** may be held within a feature such as a groove or channel on piston **109**, and is sized such that it creates an air and/or liquid tight seal between piston **109** and the inner surface of deflation plunger body **106** while allowing translation of piston **109** along deflation plunger chamber body **106** and may be fabricated from materials including, but not limited to polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, polyethylene, and the like. While piston seal **108** is depicted as an o-ring in FIG. **1**B, it should be clear to those of skill in the art that equivalent components such as gaskets may be interchanged with piston seal **108**. For example, piston seal **108** may be an integral part of piston **109**, such as one or more flanges molded, machined, or otherwise manufactured as a feature of piston **109** that provides an air and/or liquid tight seal between piston **109** and the inner surface of deflation plunger body **106**. Piston return spring **110** resides within deflation plunger chamber **107**, and has a combination of spring rate, length, pitch, wire thickness, and outer diameter such that the distal end of piston return spring **110** places a compressive load against the piston **109**. Piston return spring **110** may be fabricated from materials known in the art including but not limited to high carbon wire, alloy steel, stainless steel, nitinol, non-ferrous alloy, high-temperature alloy, and the like. Pressure release port **111** is provided to prevent pressure build up inside the deflation plunger chamber when the piston moves proximally. Plunger ring **112** may be comprised of at least one ring or a similar feature, including but not limited to flanges, indentations, wings, bars, grips, and the like, that may be used by the operator to allow the deflation plunger

102 to be held with a single hand and provide stability when advancing or retracting the deflation plunger **102**. Media release port **125**, located at the proximal side of the deflation plunger body **106**, may be incorporated as an overflow port for the excess air or fluid contained inside the syringe barrel **101**. Preferably, the pressure release port is located distal of the piston seal **108** when the piston return spring **110** is fully compressed.

FIG. **1**C shows inflation plunger **103** in detail, comprising inflation plunger tip **114**, inflation plunger tip port **115**, inflation plunger seal **116**, inflation plunger housing **117**, face seal **118**, outlet port **119**, pressure control spring **120**, pressure control piston **121**, and inflation rod **122**. The proximal end of inflation rod **122** is attached to the deflation plunger tip **104**; the two components may be joined by methods known in the art including but not limited to press fitting, adhesive bonding, ultrasonic welding, threading/tapping, overmolding, heat fusing use of a set screw, and the like. Alternatively, inflation rod **122** and deflation plunger tip **104** may be machined, molded, cast or otherwise formed as a single component. Yet another alternative configuration is to fabricate the inflation rod **122**, deflation plunger tip **104** and deflation plunger body **106** as a single component by means of machining, molding, casting or the like. Inflation rod **122** may be fabricated from materials known in the art including but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, PTFE, stainless steel, brass, aluminum, titanium and the like or combinations thereof. The proximal end of inflation plunger housing **117** is joined to the distal end of inflation rod **122** by methods known in the art that include but are not limited to press fitting, adhesive bonding, ultrasonic welding, threading/tapping, overmolding, use of a set screw, and the like and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, PTFE, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof. Alternatively, inflation plunger housing **117** and inflation rod **122** may be machined, molded, or otherwise formed as a single integrated component. Inflation plunger housing **117** further comprises outlet port **119**. Outlet port **119** may be fabricated using methods known in the art including but not limited to laser cutting and or engraving, mechanical machining, electrical discharge machining, chemical etching, and the like. Alternatively, outlet port **119** may be formed in inflation plunger housing **117** as a feature of inflation plunger housing **117** during a molding process. Inflation plunger tip **114** is joined to the distal end of inflation plunger housing **117** using methods known in the art including, but not limited to press fitting, adhesive bonding, ultrasonic welding, threading/tapping, overmolding, heat fusing, use of a set screw, and the like and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, PTFE, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof. Inflation plunger tip **114** further comprises at least one inflation plunger tip port **115** extending from the distal to proximal ends of inflation plunger tip **114**, and may be fabricated using methods known in the art including, but not limited to laser cutting and or engraving, mechanical machining, electrical discharge machining, chemical etching, and the like. Alternatively, inflation plunger tip port **115** may be formed in inflation plunger tip **114** as a feature of inflation plunger tip **114** during a molding process. Inflation plunger seal **116** may be held within a feature such as a groove or channel on inflation plunger tip **114**, and is sized such that it creates an air and/or liquid tight seal between inflation plunger tip **114** and the inner surface of smaller syringe barrel **101"** and may be fabricated from materials including, but not limited to polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, polyethylene, and the like. While inflation plunger seal **116** is depicted as an o-ring in FIG. **1**C, it should be clear to those of skill in the art that equivalent components such as gaskets may be interchanged with inflation plunger seal **116**. For example, inflation plunger seal **116** may be an integral part of inflation plunger tip **114**, such as one or more flanges molded, machined, or otherwise manufactured as a feature of inflation plunger tip **114** that provides an air and/or liquid tight seal between inflation plunger tip **114** and the inner surface of smaller syringe barrel **101"**. Face seal **118** resides inside inflation plunger housing **117** and is sized to provide an air and/or fluid tight seal when pressed against the proximal end of the inflation plunger tip **114**. Face seal **118** may be fabricated from materials known in the art including but not limited to polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber and the like. The distal face of pressure control piston **121** contacts the proximal surface of face seal **118**. Pressure control piston **121** may be joined to face seal **118** or the two components may be decoupled from each other. Methods of joining the two components may comprise but are not limited to press fitting, adhesive bonding, ultrasonic welding, threading/tapping, overmolding, use of a set screw, and the like. Pressure control piston **121** may be fabricated from materials including but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, PTFE, stainless steel, brass, aluminum, titanium and the like or combinations thereof. Alternatively, the pressure control piston **121** and the face seal **118** may be combined and may be made of a single component. Yet another alternative configuration is to eliminate the use of pressure control piston **121** by incorporating the features of the piston **121** to the face seal **119**. The proximal end of pressure control piston **121** serves as a base to stabilize the distal end of pressure control spring **120**. Pressure control spring **120** resides within inflation plunger housing **117** such that the distal end of pressure control spring **120** places a compressive load on pressure control piston **121**. Pressure control piston **121** transmits at least some of the compressive load applied by pressure control spring **120** to the proximal surface of face seal **118**, thus maintaining a seal between inflation plunger tip **114** and the distal surface of face seal **118**. Pressure control spring **120** maintains this seal until a desired pressure is exceeded; this pressure is dictated by the force (or spring force constant) of pressure control spring **120** at a given length of compression by specifying the overall length, pitch, wire thickness, wire material and outer diameter of pressure control spring **120**. Pressure control spring **120** may be fabricated from materials known in the art including but not limited to high carbon wire, alloy steel, stainless steel, nitinol, non-ferrous alloy, high-temperature alloy, and the like.

Alternatively (not shown), deflation plunger seal **105** and inflation plunger seal **116** may reside on a channel, groove, or similar feature of larger syringe barrel **101'** and smaller syringe barrel **101"**, respectively, that allow for hermetic

seals between larger syringe barrel **101'** and deflation plunger **102**, and smaller syringe barrel **101"** and inflation plunger **103**. In this embodiment, the outlet port **119** is positioned or located proximal of the inflation plunger seal **116** when the deflation plunger **102** is fully depressed into syringe barrel **101**. The outlet port **119** may be incorporated to the inflation rod **122** by way of providing an inner lumen or opening (not shown) through the length of inflation rod **122** originating from the distal end and terminating at the proximal end of the inflation rod **122**. Alternatively, the location of inflation plunger housing **117**, face seal **118**, pressure control spring **120**, and pressure control piston **121**, may be positioned proximally (not shown) by increasing the length of the inflation plunger tip **114** and decreasing the length of the inflation rod **122**, thus shifting the outlet port **119** proximal of the inflation plunger seal **116** when the deflation plunger **102** is fully depressed into syringe barrel **101**.

FIGS. **2**A-**2**E illustrate a method of the using one embodiment of the inflation/deflation syringe of the invention. The inflation/deflation syringe **100** can be used to inflate and deflate an inflatable element (not shown) of a medical device such as balloon catheter (not shown) and the like. FIG. **1**A shows the relative position of the elements of the components of the invention in an initial configuration wherein the deflation plunger **102** is advanced until the inflation plunger tip is at the distal side of the smaller syringe barrel **101"**. The syringe barrel **101** is then filled with inflation media, preferably a fluid, by fully retracting the deflation plunger **102** to the position shown in FIG. **2**B. This step can be repeated until the syringe barrel **101** is sufficiently filled with inflation media such that when the inflation/deflation syringe **100** is held vertically with the distal end pointing up, the level of the inflation media is above the distal tip of the inflation plunger **103**. Excess inflation media and/or air or air bubbles above the fluid level inside the syringe barrel **101** the can be purged out by advancing the deflation plunger **102**, while the syringe **100** is held vertically, and further advanced until the distal tip of the inflation plunger **103** is aligned at or near the proximal end of the smaller syringe barrel **101"** as shown in FIG. **2**C. A visual indicator (not shown) such as printed markers or the like, or a tactile indicator such as detents or the like, may be incorporated into the inflation/deflation syringe **100** to aid the user in filling the lumen of the syringe barrel **101** with the proper amount or volume of inflation media. The syringe port connector **124** may then be attached to the medical device inflation port. Alternatively, an inflation line extension (not shown) may be attached to the syringe port connector **124** prior to purging the excess inflation media. Once the inflation line extension is connected, excess inflation media and/or air or air bubbles above the fluid level inside the syringe barrel **101** the can be purged out by advancing the deflation plunger **102** while the syringe **100** is held vertically. At this point, the inflation line lumen (not shown) should be filled with inflation media and the distal end of the extension line can be attached to a medical device such as a balloon catheter, for example.

The balloon catheter may be prepared by aspirating the air out of the balloon inflation path by fully retracting the deflation plunger **102** and allow the air/air bubbles to be purged out (not shown). This is done by holding the syringe **100** such that the distal tip is pointed down prior to retracting the deflation plunger **102** and then releasing to neutral. FIGS. **2**D and **2**E show the subsequent one-handed inflation of the balloon catheter. The user may press on the deflation plunger ring **112** until the inflation plunger tip **114** is at the end of the advancement stroke. The balloon may then be deflated by fully retracting the deflation plunger **102**. Once the balloon of the medical device is deflated, the deflation plunger **102** can be released and place back to neutral position.

FIGS. **3**A and **3**B detail one unique aspect of the preferred embodiment; the pressure control mechanism incorporated in the design of the inflation plunger **103** which limits the maximum pressure being applied to the medical device. The maximum internal pressure generated inside the distal portion of smaller syringe barrel **101"** during the advancement of the inflation plunger **103** is limited or regulated by the pressure control mechanism contained inside the inflation plunger housing **117**. The pressure control mechanism is comprised of the face seal **118**, pressure control piston **121** and pressure control spring **120**. The maximum inflation pressure is determined or regulated by the degree or amount of compression force applied by the pressure control spring **120** to the pressure control piston **121** that presses the face seal **118** against the proximal face of the inflation plunger tip **114**. FIG. **3**A shows the pressure control mechanism in a closed state, wherein the pressure in the smaller syringe barrel **101"** distal to the inflation plunger seal **116** is below that of a pre-determined value. Under these conditions, outlet port **119** is closed and there is no fluid and/or air flow path between the distal portion of smaller syringe barrel **101"** and larger syringe barrel **101'**. FIG. **3**B illustrates the pressure control mechanism in the open state, wherein the internal pressure inside the distal portion of the smaller syringe barrel **101"** exceeds a pre-determined value. In this state, the internal pressure inside the distal portion of smaller syringe barrel **101"** exceeds that of the pre-determined pressure exerted by the face seal **118** against the inflation plunger tip, compressing the pressure control spring **120** and moving face seal **118** proximally. The movement of face seal **188** opens a flow path at the contact interface between face seal **118** and inflation plunger tip **114**. Further movement of the face seal **118** to a position proximal to outlet port **119** creates a flow path between the distal portion of smaller syringe barrel **101"** and larger syringe barrel **101'**. The excess pressure inside the distal portion of smaller syringe barrel **101"** is reduced as the inflation media flows through the outlet port **119**, along the proximal portion of smaller syringe barrel **101"**, and into larger syringe barrel **101'**. When the internal pressure inside the distal portion of smaller syringe barrel **101"** falls below the pre-determined level, compression spring **120** expands and applies force to pressure control piston **121**, which in turn moves distally and re-establishes the interface between face seal **118** and the proximal face of inflation plunger tip **114**. The value of the pre-determined pressure may be adjusted by changing the force constant of the compression spring **120**, the resting length of the compression spring **120**, the distance between outlet port **119** and the proximal edge of inflation plunger tip **114**, the static or dynamic friction between the face seal and the internal surface of the inflation plunger housing **117**, the static or dynamic friction between the pressure control piston **121** and the inflation plunger housing **117**, or the durometer of face seal **118** and/or pressure control piston **121** among other methods known in the art. While the pressure control mechanism has been depicted as a spring and seal combination in this embodiment, other valve and/or seal mechanisms including but not limited to ball valves, duckbill valves, umbrella valves, check valves, diaphragms, shuttling valves, flap valves and the like may be incorporated into the mechanism.

Another unique aspect of the inflation/deflation syringe **100** of the invention is the capacity to both inflate and deflate

the balloon of a medical device by advancing or retracting the coupled deflation plunger **102** and inflation plunger **103** simultaneously inside a combined or integrated syringe barrel **101** that comprises two different diameters and/or volumes. FIG. **4**A illustrates a typical tandem syringe set up two sizes of syringe body are connected and arranged in series with the smaller syringe body **401** positioned distal to the larger syringe body **402**. The syringe plunger **403** in such a system is sized to reside within the tandem syringe; this may be accomplished through the use of a stepped design that has a smaller distal section **403"** that matches the smaller syringe body **401** and a larger proximal section **403'** that matches the proximal syringe body **402** such that the syringe plunger **403** can translate along the length of the syringe body. In these types of systems, it is often not possible to generate a sufficiently high internal pressure inside the smaller syringe body **401** (and in any medical equipment connected to the smaller syringe body). Once the distal plunger seal **404** engages and seals against the inside wall of the smaller syringe body chamber **401** (as shown in FIG. **4**B), the inflation fluid is trapped within the larger syringe body chamber. The incompressible inflation fluid trapped between distal plunger seal **404** and proximal plunger seal **405** then prevents the syringe plunger **403** from advancing further and increasing the pressure inside the smaller syringe body **401**.

The unique design of the present invention illustrated in FIGS. **5**A and **5**B allows the plungers **102** and **103** to be advanced further by incorporating a deflation plunger tip port **113** that allows the incompressible fluid trapped inside the larger syringe barrel **101'** to be displaced and transferred to the deflation plunger chamber **107**. FIG. **5**A depicts the arrangement of the components of the invention at the point when the inflation plunger seal **116** initially contacts and seals against the inner wall of the smaller syringe barrel **101"**. The distal face of the piston **109** is in contact with the proximal face of the deflation plunger tip **104**, closing the potential flow path through the deflation plunger tip port **113**. FIG. **5**B depicts the arrangement of the components of the invention after the syringe plungers **102** and **103** are further advanced distally. As syringe plungers **102** and **103** translate distally, the piston **109** and piston seal **108** assembly is pushed back proximally and the incompressible inflation fluid is directed through deflation plunger tip port **113** and transferred inside the deflation plunger chamber **107**. The piston **109** and piston seal **108** assembly provides a leak free seal that keeps the inflation fluid inside the deflation plunger chamber **107**. When the plungers **102** and **103** are retracted for deflation (not shown), the incompressible inflation fluid inside the deflation plunger chamber **107** is returned to smaller syringe barrel **101'** through deflation plunger tip port **113**. The retraction of syringe plungers **102** and **103** creates a negative pressure inside the larger syringe barrel **101'**. The negative pressure (with respect to the ambient pressure on the proximal side of the piston **109** and piston seal assembly **108**) draws the inflation fluid into larger syringe barrel **101'** and pulls the piston **109** and piston seal **108** assembly distally within the deflation plunger chamber **107**. The piston return spring **110** maintains the piston **109** in a normally biased position against the proximal face of deflation plunger tip **104** when the pressure in larger syringe barrel **101'** is less than that applied by the piston return spring **110** to the piston **109**.

Yet another alternative configuration of the present invention is shown in FIG. **6**. Inflation/deflation syringe **600** comprises a syringe body **601**, a deflation plunger **603**, an inflation plunger **604**, and movable plunger **606**. As described earlier for syringe body **601**, the syringe body **601** is comprised of at least two integrated syringe barrels with at least two different cross sectional inner diameters, preferably oriented in series or tandem configuration. The syringe body **601** configuration in the preferred embodiment comprises of a smaller volume syringe body (e.g. with a volume capacity of about 1 ml), located in series and preferably distal of the larger volume syringe body (e.g. with a volume capacity equal to or greater than 5 ml). The smaller volume syringe body is dimensioned to have a relatively small inner diameter and is used as the inflation chamber whereby the larger volume syringe body is dimensioned to have a larger inner diameter relative the smaller volume syringe barrel and is used as the deflation chamber as well as a reservoir for inflation fluid media such as air or liquid. Syringe body **601** also comprises at least one ring **602** or a similar feature, including but not limited to flanges, indentations, wings, bars, grips, and the like, that may be used by the operator to allow the syringe body to be single-handedly held. Deflation plunger **603** further comprises a deflation plunger tip, deflation plunger tip port, deflation plunger seal, and a deflation plunger chamber as described earlier for deflation plunger **103**. Inflation plunger **604** further comprises an inflation plunger tip, an inflation plunger tip port, an inflation plunger seal, an inflation plunger housing, a face seal, an outlet port, a pressure control spring, a pressure control piston, and an inflation rod as described earlier for inflation plunger **104**. Deflation plunger **603** further comprises at least one ring **605** or a similar feature, including but not limited to flanges, indentations, wings, bars, grips, and the like, that facilitate movement of deflation plunger **603** with respect to syringe body **601**. Movable plunger **606** is slidably disposed within the lumen of deflation plunger **603** and comprises a gasket that provides an air and/or fluid tight seal between movable plunger **606** and the inner surface of deflation plunger **603** and at least one ring **607** or a similar feature, including but not limited to flanges, indentations, wings, bars, grips, and the like, that facilitate movement of movable plunger **606** with respect to syringe body **601** and/or deflation plunger **603**. A return spring such as return spring **110** may or may not be present. If present, the return spring would reside in the lumen of deflation plunger **603** and bias the distal tip of the movable plunger against the proximal face of the deflation plunger tip component of the deflation plunger **603**.

FIGS. **7**A-**7**C illustrate a method of using this composition of the invention. FIG. **7**A depicts the inflation/deflation syringe **600** in a prepped state, wherein the inflation plunger **604**, deflation plunger **603**, and movable plunger **606** are retracted and the lumen of the syringe body **601** is filled with the inflation media. The volume or amount of inflation fluid drawn into the lumen of the syringe body **601** will correspond to the volume needed to fill the balloon and generate high pressure within the balloon. A visual indicator (not shown) such as printed markers or the like, or a tactile indicator such as detents or the like, may be incorporated into the inflation/deflation syringe **600** to aid the user in filling the lumen of the syringe body **601** with the proper amount or volume of inflation media. The distal end of movable syringe **606** is seated against the distal wall of deflation plunger **603**. FIG. **7**B depicts the state of the inflation/deflation syringe **600** as movable plunger **606** begins to advance in the distal direction, introducing the inflation media into an attached medical device (not shown), such as a balloon catheter. As the void volume of the medical device is filled with inflation media and the balloon begins to expand, the pressure in the balloon increases. High

pressure inflation of the balloon is achieved by fully depressing the deflation plunger **603** and inflation plunger **604** as shown in FIG. **7**C. This may be done by grasping rings **602** and **605** and sliding ring **605** distally towards ring **602**. Deflation of the balloon (not shown) may be accomplished by grasping rings **602** and **605** and sliding ring **605** proximally until a sufficient vacuum is generated in the lumen of syringe body **601** such that the balloon is deflated in an appropriate length of time. The utility of this type of design configuration may be particularly useful when inflating a large balloon diameter and/or long balloon length where the volume of inflation media required to fill the balloon prior to generating high pressure is more than the volume capacity of the small syringe commonly used to inflate and pressurize the balloon.

In yet another embodiment, the pressure control mechanism comprised of the face seal **118**, pressure control piston **121**, pressure control spring **120**, along with the associated components such as inflation plunger tip port **115**, inflation plunger housing **117** and outlet port **119** can be eliminated and replaced with a standard inflation plunger (not shown) and seal **116** configuration. In this configuration, the internal pressure generated inside the smaller syringe barrel **101"** is not limited. However, this internal pressure can be monitored by adding a pressure gage or indicator or sensor with indicator (not shown) at the distal end of the syringe body where it is in communication with the inflation fluid path. The pressure gage or indicator set up is typically seen on standard inflation devices as described earlier. The difference between the device described in this invention and that of a typical inflation device is the ability of the user to use a single hand to generate very high pressure inflation in a controlled manner. Very high inflation pressure as defined in this embodiment is that pressure in excess of 4 atmospheres. Together with the high pressure inflation capability, sufficient vacuum can be generated on the same device which facilitates rapid balloon deflation of a medical device.

FIGS. **8**A-**8**B illustrate another embodiment of the invention. Inflation/deflation syringe **800** is comprised of a deflation syringe **801**, an inflation syringe **802**, a plunger **804**, inflation syringe seal **805**, port connector **825**, and at least one grip **803**. The distal end of the deflation syringe **801** is connected to a port in the sidewall of inflation syringe **802**. Deflation syringe **801** may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, PET, PEEK, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof, and may be transparent, translucent, opaque, or any gradient thereof. The inflation syringe **802** may be smaller (e.g. with a volume capacity of about 1 ml) than the deflation syringe **801** (e.g. with a volume capacity equal to or greater than 5 ml) and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, PET, PEEK, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof, and may be transparent, translucent, opaque, or any gradient thereof. The inflation syringe **802** may be dimensioned to have a relatively small inner diameter and is used as the inflation chamber whereby the deflation syringe **801** may be dimensioned to have a larger inner diameter relative to inflation syringe **802** and is used as the deflation chamber as well as a reservoir for inflation media such as air or liquid. While grip **803** is shown as a ring, it should be obvious that other features that enable and/or ease handling of inflation/deflation syringe **800** may be freely interchanged with grip **803** including, but not limited to flanges, cantilevers, overmolded components of durometer different from that of deflation syringe **801** and inflation syringe **802**, ridges, triggers, wings, and the like. Plunger **804** is sized such that deflation plunger **806** is coaxially disposed within deflation syringe **801** and inflation plunger **807** is coaxially disposed within inflation syringe **802**. Port connector **825** may include but is not limited to fixed male or female luer lock fittings, rotating male or female luer lock fittings, hose barbs, slip luers, quick release fittings, and the like. In place of a port connector **825** provided at the distal end of the inflation syringe **802**, an extension line or tubing (not shown) may be permanently attached to the distal end of the inflation siring **802** and the port connector **825** may attached to the distal end of the extension line (not shown).

As shown in FIG. **8**B, plunger **804** comprises a deflation plunger **806**, and inflation plunger **807**, grip **808**, and pressure release port **809**. Deflation plunger **806** further comprises deflation plunger tip **812**, deflation plunger tip port **813**, deflation plunger seal **811**, deflation plunger chamber **816**, piston seal **814**, piston **810**, and piston return spring **815**. Deflation plunger **806** is sized to fit coaxially within deflation syringe **801** and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, PET, PEEK, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof, and may be transparent, translucent, opaque, or any gradient thereof. Deflation plunger tip **812** is joined to the distal end of deflation plunger **806** by methods known in the art including, but not limited to press fitting, adhesive bonding, ultrasonic welding, threading/tapping, overmolding, heat fusing, use of a set screw, and the like and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, PTFE, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof. Furthermore, deflation plunger tip **812** and deflation plunger **806** may be integrated and made as single component by means of commonly known fabrication techniques such as machining, injection molding, blow molding, casting, and the like or combinations thereof. Deflation plunger tip **812** further comprises at least one deflation plunger tip port **813**. Deflation plunger tip port **813** may be fabricated using methods known in the art including, but not limited to laser cutting and or engraving, mechanical machining, electrical discharge machining, chemical etching, and the like. Alternatively, deflation plunger tip port **820** may be formed in deflation plunger tip **812** as a feature of deflation plunger tip **812** during a molding process. Deflation plunger seal **811** is sized and arranged such that it provides an air and/or fluid tight seal between the deflation plunger tip **812** and the inner surface of deflation syringe **801** and may be fabricated from materials including, but not limited to polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, polyethylene, and the like. While deflation plunger seal **811** is depicted as an o-ring in FIG. **8**B, it should be clear to those of skill in the art that equivalent components such as gaskets may be interchanged with deflation plunger seal **811**. For example, deflation seal **811** may be an integral part of deflation plunger tip **812**, such as one or more flanges molded, machined, or otherwise manufactured as a feature of deflation plunger **812** that provides an air and/or liquid tight seal between deflation plunger tip **812** and the inner

surface of deflation syringe **801**. Piston **810** coaxially resides within deflation plunger chamber **816** and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, PTFE, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof. Piston **810** is biased by return spring **815** such that the distal face of piston **810** is positioned against the proximal face of deflation plunger tip **812**. Piston seal **814** may be held within a feature such as a groove or channel on piston **810**, and is sized such that it creates an air and/or liquid tight seal between piston **810** and the inner surface of deflation plunger **806** while allowing translation of piston **810** along deflation plunger chamber **816** and may be fabricated from materials including, but not limited to polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, polyethylene, and the like. While piston seal **814** is depicted as an o-ring in FIG. **8**B, it should be clear to those of skill in the art that equivalent components such as gaskets may be interchanged with piston seal **814**. For example, piston seal **814** may be an integral part of piston **810**, such as one or more flanges molded, machined, or otherwise manufactured as a feature of piston **810** that provides an air and/or liquid tight seal between piston **810** and the inner surface of deflation plunger **806**. Piston return spring **815** resides within deflation plunger chamber **816**, and has a combination of spring rate, length, pitch, wire thickness, and outer diameter such that the distal end of piston return spring **815** places a compressive load against the piston **810**. Piston return spring **815** may be fabricated from materials known in the art including but not limited to high carbon wire, alloy steel, stainless steel, nitinol, non-ferrous alloy, high-temperature alloy, and the like. Pressure release port **809** is provided to prevent pressure build up inside the deflation plunger chamber **816** when the piston **810** moves proximally.

Inflation plunger **807** further comprises inflation plunger tip **823**, inflation plunger tip port **822**, inflation plunger seal **821**, inflation plunger housing **817**, face seal **824**, outlet port **820**, pressure control spring **818**, and pressure control piston **819**. Inflation plunger housing **817** is joined to the distal end of inflation plunger **806** using methods known in the art including, but not limited to press fitting, adhesive bonding, ultrasonic welding, threading/tapping, overmolding, heat fusing, use of a set screw, and the like and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, PTFE, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof. Alternatively, inflation plunger housing **817** and inflation plunger **806** may be machined, molded, or otherwise formed as a single integrated component. Inflation plunger housing **817** further comprises outlet port **820**. Outlet port **820** may be fabricated using methods known in the art including but not limited to laser cutting and or engraving, mechanical machining, electrical discharge machining, chemical etching, and the like. Alternatively, outlet port **820** may be formed in inflation plunger housing **817** as a feature of inflation plunger housing **817** during a molding process. Inflation plunger tip **823** is joined to the distal end of inflation plunger housing **817** using methods known in the art including, but not limited to press fitting, adhesive bonding, ultrasonic welding, threading/tapping, overmolding, heat fusing, use of a set screw, and the like and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, PTFE, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof. Inflation plunger tip **823** further comprises at least one inflation port **822** extending from the distal to proximal ends of inflation plunger tip **823**, and may be fabricated using methods known in the art including, but not limited to laser cutting and or engraving, mechanical machining, electrical discharge machining, chemical etching, and the like. Alternatively, inflation port **822** may be formed in inflation plunger tip **823** as a feature of inflation plunger tip **823** during a molding process. Inflation plunger seal **821** may be held within a feature such as a groove or channel on inflation plunger tip **823**, and is sized such that it creates an air and/or liquid tight seal between inflation plunger tip **823** and the inner surface of inflation syringe **802** and may be fabricated from materials including, but not limited to polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, polyethylene, and the like. While inflation plunger seal **821** is depicted as an o-ring in FIG. **8**B, it should be clear to those of skill in the art that equivalent components such as gaskets may be interchanged with inflation plunger seal **821**. For example, inflation plunger seal **821** may be an integral part of inflation plunger tip **823**, such as one or more flanges molded, machined, or otherwise manufactured as a feature of inflation plunger tip **823** that provides an air and/or liquid tight seal between inflation plunger tip **823** and the inner surface of inflation syringe **802**. Face seal **824** resides inside inflation plunger housing **817** and is sized to provide an air and/or fluid tight seal when pressed against the proximal end of the inflation plunger tip **823**. Face seal **824** may be fabricated from materials known in the art including, but not limited to polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber and the like. Pressure control piston **819** coaxially resides within inflation plunger housing **817** and may be fabricated from materials known in the art including, but not limited to polycarbonate, polypropylene, polymethylmethacrylate, polyurethane, nylon, Pebax, PET, PEEK, Delrin®, polychloroprene, silicone rubber, nitrile rubber, Viton®, EPDM, butyl rubber, natural rubber, PTFE, stainless steel, brass, aluminum, titanium, borosilicate glass, ceramics, and the like or combinations thereof. Pressure control piston **819** is biased by pressure control spring **818** such that the distal face of pressure control piston **819** contacts the proximal surface of face seal **824**. Pressure control piston **819** may be joined to face seal **824** or the two components may be decoupled from each other. Methods of joining the two components may comprise, but are not limited to press fitting, adhesive bonding, ultrasonic welding, threading/tapping, overmolding, use of a set screw, and the like. Alternatively, pressure control piston **819** and face seal **824** may be manufactured as a single unit. The proximal end of pressure control piston **819** serves as a base to stabilize the distal end of pressure control spring **818**. Pressure control spring **818** resides within inflation plunger housing **817** such that the distal end of pressure control spring **818** places a compressive load on pressure control piston **819**. Pressure control piston **819** transmits at least some of the compressive load applied by pressure control spring **818** to the proximal surface of face seal **824**, thus maintaining a seal between inflation plunger tip **823** and the

distal surface of face seal **824**. Pressure control spring **818** maintains this seal until a desired pressure is exceeded; this pressure is dictated by the force (or spring force constant) of pressure control spring **818** at a given length of compression by specifying the overall length, pitch, wire thickness, wire material and outer diameter of pressure control spring **818**. Pressure control spring **818** may be fabricated from materials known in the art including, but not limited to high carbon wire, alloy steel, stainless steel, nitinol, non-ferrous alloy, high-temperature alloy, and the like.

While grip **808** is shown as a ring, it should be obvious that other features that enable and/or ease handling of inflation/deflation syringe **800** may be freely interchanged with grip **808** including, but not limited to flanges, cantilevers, overmolded components of durometer different from that of plunger **804**, ridges, triggers, wings, and the like that may be used by the operator to allow the inflation/deflation syringe **800** to be held with a single hand and provide stability when advancing or retracting the plunger **804**.

The pressure control mechanism of the embodiment of the invention shown in FIGS. **8**A and **8**B provides the same function as that described in FIGS. **3**A and **3**B. Similarly, while the pressure control mechanism has been depicted as a spring and seal combination in this embodiment, other valve and/or seal mechanisms including but not limited to ball valves, duckbill valves, umbrella valves, check valves, diaphragms, shuttling valves, flap valves and the like may be incorporated into the mechanism.

The design of the inflation/deflation syringe **800** allows inflation media inside the deflation syringe **801** to be displaced and transferred to the deflation plunger chamber **816**. As plunger **804** translates distally and the pressure within deflation syringe **801** exceeds a pre-set value, the piston **810** and piston seal **814** assembly is pushed back proximally and the inflation media is directed through deflation plunger tip port **813** and into deflation plunger chamber **816**. The piston **810** and piston seal **814** assembly provides a leak free seal that keeps the inflation fluid inside the deflation plunger chamber **816**. When the plunger **804** is retracted for deflation the inflation media inside the deflation plunger chamber **816** is returned to deflation syringe **801** through deflation plunger tip port **813**. The retraction of syringe plunger **804** creates a negative pressure inside the deflation syringe **801**. The negative pressure (with respect to the ambient pressure on the proximal side of the piston **810** and piston seal **814**) draws the inflation media into deflation syringe **801** and pulls the piston **810** and piston seal **814** assembly distally within the deflation plunger chamber **816**. The piston return spring **815** maintains the piston **810** in a normally biased position against the proximal face of deflation plunger tip **812** when the pressure in deflation syringe **801** is less than that applied by the piston return spring **815** to the piston **810**.

Alternatively (not shown), deflation plunger seal **811** and inflation plunger seal **821** may reside on a channel, groove, or similar feature of deflation syringe **801** and inflation syringe **802**, respectively, that allows for hermetic seals between deflation syringe **801** and deflation plunger **806**, and inflation syringe **802** and inflation plunger **807**. In this embodiment, the outlet port **820** is positioned or located proximal of the inflation plunger seal **821** when the plunger **804** is fully depressed into deflation syringe **801** and inflation syringe **802**. The outlet port **820** may be incorporated to the inflation rod **807** by way of providing an inner lumen or opening (not shown) through the length of inflation rod **807** originating from the distal end and terminating at the proximal end of the inflation rod **807**. Alternatively, the location of inflation plunger housing **817**, face seal **824**, pressure control spring **818**, and pressure control piston **819**, may be positioned proximally (not shown) by increasing the length of the inflation plunger tip **823** and decreasing the length of the inflation rod **807**, thus shifting the outlet port **820** proximal of the inflation plunger seal **821** when the plunger **804** is fully depressed into deflation syringe **801** and inflation syringe **802**.

FIG. **9**A-**9**C illustrate a method of the using one embodiment of the inflation/deflation syringe of the invention. The inflation/deflation syringe **800** can be used to inflate and deflate an inflatable element (not shown) of a medical device such as balloon catheter (not shown) and the like. FIG. **9**A shows the relative position of the elements of the components of the invention when inflation media has been fully drawn into the deflation syringe **801** and inflation syringe **802**. Excess inflation media and/or air or air bubbles above the media level inside the deflation syringe **801** and inflation syringe **802** can be purged out by advancing the plunger **804**, while the syringe **800** is held vertically. A visual indicator (not shown) such as printed markers or the like, or a tactile indicator such as detents or the like, may be incorporated into the inflation/deflation syringe **800** to aid the user in filling the lumens of the deflation syringe **801** and/or inflation syringe **802** with the proper amount or volume of inflation media. The port connector **825** may then be attached to the medical device inflation port. Alternatively, an inflation line extension (not shown) may be attached to the port connector **825** prior to purging the excess inflation media. Once the inflation line extension is connected, excess inflation media and/or air or air bubbles above the fluid level inside the deflation syringe **801** and inflation syringe **802** can be purged out by advancing the plunger **804**, while the syringe **800** is held vertically. At this point, the inflation line lumen (not shown) should be filled with inflation media and the distal end of the extension line can be attached to a medical device such as a balloon catheter, for example. A balloon catheter, for example, may be prepared by aspirating the air out of the balloon inflation path by fully retracting the plunger **804** and allowing the air/air bubbles to be purged out (not shown). This is done by holding the syringe **800** such that the distal tip is pointed down prior to retracting the plunger **804** and then releasing to neutral. FIGS. **8**B and **8**C show the subsequent one-handed inflation of the balloon catheter. The user may advance grip **808** distally until the plunger **804** is at the end of the advancement stroke. The balloon may then be deflated by fully retracting the plunger **804**. Once the balloon of the medical device is deflated, grip **808** can be released return plunger **804** to a neutral (equilibrated pressure) position.

In yet another embodiment of inflation/deflation syringe **800**, the pressure control mechanism comprised of the face seal **820**, pressure control piston **819**, pressure control spring **818**, along with the associated components such as inflation plunger tip port **822**, inflation plunger housing **817** and outlet port **820** can be eliminated and replaced with a standard inflation plunger (not shown) and seal **821** configuration. In this configuration, the internal pressure generated inside the inflation syringe **802** is not limited. However, this internal pressure can be monitored by adding a pressure gage or indicator or sensor with indicator (not shown) at the distal end of the syringe body where it is in communication with the inflation fluid path. The pressure gage or indicator set up is typically seen on standard inflation devices as described earlier. The difference between the device described in this invention and that of a typical inflation device is the ability of the user to use a single hand to generate very high pressure inflation in a controlled

manner. Very high inflation pressure as defined in this embodiment is that pressure in excess of 4 atmospheres. Together with the high pressure inflation capability, sufficient vacuum can be generated on the same device which facilitates rapid balloon deflation of a medical device.

Furthermore (not shown), the inflation/deflation syringes **100**, **600**, and **800** may comprise locking mechanisms known in the art that can be engaged or disengaged, such as those taught in U.S. Pat. No. 5,215,536 and herein incorporated in full by reference, between the syringe plungers and syringe barrels that allow or enable a desired pressure or vacuum to be maintained within inflation/deflation syringes **100**, **600**, and **800**.

In yet another embodiment of this invention, inflation/deflation syringes **100**, **600**, and **800** may be used to deliver a low volume of inflation media in a controlled manner. This may have application in the inflation of a low pressure balloon, for example. In this use, a graduation or marking on the syringe body may be aligned with a feature on the inflation and/or deflation plungers to signal the delivery of an appropriate volume of inflation media.

The preceding merely illustrates the principles of the invention. It will be appreciated that those skilled in the art will be able to devise various arrangements, which, although not explicitly described or shown herein, embody the principles of the invention, and are included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the invention and the concepts contributed by the inventors to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and embodiments of the invention as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present invention, therefore, is not intended to be limited to the exemplary embodiments shown and described herein. Rather, the scope and spirit of present invention is embodied by the appended claims.

What is claimed is:

1. An inflation/deflation syringe that generates pressure or delivers a controlled volume, comprising:

a syringe barrel comprising a first smaller diameter chamber and an adjacent second larger diameter chamber;

a syringe plunger comprising multiple diameters sized to fit within the syringe barrel, wherein a syringe plunger segment of large diameter is hollow and in fluid communication with the second larger diameter chamber of the syringe barrel and an adjacent fixed syringe plunger segment of small diameter comprising a solid rod sized to fit within the first smaller diameter chamber of the syringe barrel; and

a piston and/or seal disposed and hermetically sealed within an inner chamber of the syringe plunger segment of large diameter, and

wherein the multiple chambers of the syringe barrel are in fluid communication with one another when the syringe plunger is fully retracted within the syringe barrel.

2. The inflation/deflation syringe of claim **1**, wherein all chambers of the syringe barrel are directly connected in serial and/or parallel arrangements.

3. The inflation/deflation syringe of claim **1**, wherein the first smaller diameter chamber and the second larger diameter chamber of the syringe barrel are in parallel arrangement.

4. The inflation/deflation syringe of claim **1**, wherein the small diameter syringe plunger segment is directly connected to and in serial or parallel arrangement with the large syringe plunger segment.

5. The inflation/deflation syringe of claim **1**, wherein each syringe plunger segment comprises a sealing member.

6. The inflation/deflation syringe of claim **5**, wherein the sealing member is located at the distal end of each syringe plunger segment.

7. The inflation/deflation syringe of claim **1**, wherein each syringe barrel chamber comprises a sealing member.

8. The inflation/deflation syringe of claim **1**, wherein the small diameter syringe plunger segment further comprises a pressure regulating or limiting mechanism.

9. The inflation/deflation syringe of claim **1**, wherein a pressure gage or pressure monitoring indicator is connected to the first smaller diameter chamber of the syringe barrel.

10. The inflation/deflation syringe of claim **1**, wherein the first smaller diameter chamber of the syringe barrel chamber in conjunction with the syringe plunger segment of small diameter provides high pressure inflation or controlled volume delivery.

11. The inflation/deflation syringe of claim **1**, wherein the second larger diameter chamber of the syringe barrel chamber provides vacuum and/or a reservoir for an inflation media.

12. The inflation/deflation syringe of claim **11**, further comprising a media release port in large diameter syringe plunger segment.

13. The inflation/deflation syringe of claim **11**, wherein the inflation media is gas and/or liquid.

14. The inflation/deflation syringe of claim **1**, wherein high pressure inflation or a controlled volume delivery can be generated using a single hand and the syringe plunger can be retracted post inflation or post controlled volume delivery using a single hand.

15. The inflation/deflation syringe of claim **1**, wherein the inflation/deflation syringe may be locked to maintain a desired inflation pressure.

16. The inflation/deflation syringe of claim **1**, wherein the inflation/deflation syringe may be locked to maintain a desired deflation pressure or vacuum.

17. The inflation/deflation syringe of claim **1**, wherein the piston and/or seal disposed and hermetically sealed within the inner chamber of the syringe plunger of large diameter is biased towards the distal end of the inner chamber of the syringe plunger of large diameter under neutral pressure.

18. The inflation/deflation syringe of claim **1**, further comprising at least one marker to indicate a desired fill volume of inflation media.

19. A method of using the inflation/deflation syringes of claim **1**, comprising;

drawing inflation media into the syringe barrel chambers;

expelling excess gas and/or inflation media from the syringe barrel chambers;

connecting to the inflation port of a medical device;

transferring inflation media into the medical device to a desired pressure and/or volume, and

withdrawing inflation media from the medical device when desired to return the pressure and/or volume of the inflation media within the medical device to a desired level.

20. The method of claim 19, wherein the volume of inflation media drawn into the inflation/deflation syringe does not exceed the volume of the larger diameter syringe barrel.

21. The method of claim 19, wherein the inflation/deflation syringe is filled with a desired volume of inflation media using visual markers or tactile feedback.

22. The method of claim 19, wherein the inflation/deflation syringe is locked in position after transferring inflation media into the medical device to maintain the desired pressure and/or volume of media in the medical device.

23. The method of claim 19, wherein the inflation/deflation syringe is locked in position after withdrawing inflation media from the medical device to attain a desired pressure and/or volume of media in the medical device.

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